REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on July 20, 2010. The Office Action provided a three-month shortened statutory period in which to respond, ending on October 20, 2010. Accordingly, this amendment is timely submitted. No fees are believed due with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Claims 1-4, 6-14 and 16-28 are currently pending. Claims 6, 12 and 18-22 were previously withdrawn. Claims 5, 15 and 29 were previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-4, 7-11, 13-14, 16, 17 and 23-28 are rejected under 35 U.S.C. §103, and Claims 1 and 23-25 are rejected under 35 U.S.C. §102. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application. For the reasons set forth below, Applicant respectfully submits that the rejections should be reconsidered and withdrawn.

In response to the Office Action, Claims 1-4, 17, 23-25 and 28 have been amended. The amendments do not add new matter and are supported in the specification at, for example, page 5, lines 1-4. In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

In the Office Action, Claims 1-4, 7-11, 13-14, 16-17 and 23-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,077,828 to Abbruzzese, et al. ("*Abbruzzese*") as evidenced by U.S. Patent No. 4,112,123 Roberts ("*Roberts*") in view of U.S. Patent No. 6,420,342 to Hageman, et al. ("*Hageman*") and U.S. Patent No. 6,953,679 to Salvati, et al. ("*Salvati*"). Claims 1-4, 7-11, 13-14, 16-17 and 23-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Abbruzzese* in view of U.S. Publication No. 2003/0119888 to Allen et al. ("*Allen*") and Sports Supplement Review, 1997, pp. 66-70 to Phillips Bill ("*Phillips*"). Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Currently amended independent Claims 1-3, 17, 23-25 and 28 recite, in part, compositions having leucine, valine in an amount of about 8% to about 10% by weight based on the weight of total amino acids, and at least one essential amino acid selected from the group consisting of isoleucine, lysine, methionine, phenylalanine, threonine, tryptophan, histidine, and combinations thereof in free and/or salt form, wherein said leucine, in free and/or salt form. The amendments do not add new matter and are supported in the specification at, for example, page 5, lines 1-4. Applicant has found that when dietary intake is limited below the optimal level for physiological or patho-physiological reasons, a dietary supplement must be more effective than normal food intake in order to provide a benefit. This is because in this circumstance, when a dietary supplement is given, normal food intake is likely to be reduced by a calorically equivalent amount. Consequently, a supplement designed to limit cancer cachexia, for example, should stimulate muscle protein synthesis to a greater extent than normal food intake and should not interfere with the response to meal intake. Trials of conventional nutritional supplements in patients with cancer cachexia have failed to show appreciable benefit in terms of weight gain or quality of life. Accordingly, there is a need for effective nutritional approaches capable of treating, preventing or ameliorating the effects of tumor-induced weight loss due to, for example, cancer cachexia and/or anorexia.

Applicant has surprisingly found that a formulation containing free essential amino acids as compared to a formulation containing free essential and non-essential amino acids or intact protein alone is optimal. See specification, Examples 1-2. Applicant has also found that nutritional compositions comprising a mixture of essential amino acids in free form and/or in salt form that has particularly high amounts of leucine had a stimulatory effect on muscle protein synthesis. See specification, Example 3.

In addition, Applicant has surprisingly and unexpectedly found that particularly useful compositions for promotion of muscle protein synthesis or controlling tumor-induced weight loss, such as cachexia, e.g. cancer cachexia, may be obtained by combining essential amino acids in free form and/or in salt form with intact protein. See specification, Example 2. The effect of such a combination is greater than the effect that can be achieved with either type of combination partner alone. In contrast, Applicant respectfully submits that the cited references fail to disclose or suggest every element of the present claims.

Abbruzzese, *Roberts*, *Hageman*, *Salvati*, *Allen* and *Phillips* fail to disclose or suggest compositions having leucine, valine in an amount of about 8% to about 10% by weight based on the weight of total amino acids, and at least one essential amino acid selected from the histidine, and combinations thereof in free and/or salt form, wherein said leucine, in free and/or salt form as required, in part, by currently amended independent Claims 1-3, 17, 23-25 and 28. Instead, *Abbruzzese* is directed to methods and nutritional compositions for preventing and treating cachexia and anorexia. The compositions of *Abbruzzese* include effective amounts of (1) ω3 fatty acids, such as α-linolenic acid, stearidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid or mixtures thereof; (2) branched-chain amino acids, such as valine, leucine, isoleucine or mixtures thereof; with or without reduced levels of tryptophan and 5-hydroxytryptophan; and (3) an anti-oxidant system selected from the group consisting of beta-carotene, vitamin C, vitamin E, selenium, or mixtures thereof. See, e.g., *Abbruzzese*, column 3, lines 15-56. However, at no place in the disclosure does *Abbruzzese* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims. Indeed, at best, *Abbruzzese* discloses only 5.9% valine. See, *Abbruzzese*, Table 4.

Hageman generally describes a nutritional, pharmaceutical or dietetic preparation that includes effective amounts of ribose and folic acid, optionally combined with other components, such as niacin, histidine, glutamine, orotate, vitamin B6 and other components. See *Hageman*, column 5, lines 8-52. *Hageman* also discloses products having the following mixture of amino acids as beneficial for muscle growth when consumed in an amount of more than 2 and preferably more than 4 g per daily dose: 3-10 wt % histidine, 5-15 wt % isoleucine, 10-23 wt % leucine, 10-23 wt % lysine, 5-15 wt % methionine, 5-15 wt % phenylalanine, 5-15 wt % threonine. See *Hageman*, column 6, line 62-column 7, line 1. At no place in the disclosure does *Hageman* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims. Indeed, at best, *Hageman* discloses only 3.5% valine. See, *Hageman*, Example 2.

Salvati generally describes fused cyclic compounds and methods of using such compounds in the treatment of nuclear hormone receptor-associated diseases such as cancer and immune disorders and pharmaceutical compositions containing such compounds. See

Salvati, Abstract. At no place in the disclosure does *Salvati* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims.

Roberts is entirely directed to a balanced food composition for oral ingestion and producing low residues and diminished stoolings. See, *Roberts*, Abstract. *Roberts* is cited by the Patent Office for the disclosure of the amounts of amino acids in whey proteins. At no place in the disclosure does *Roberts* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims.

Allen is entirely directed to a composition for stimulating muscle growth having an effective amount of L-arginine. See, *Allen*, Abstract. As shown by Example 1 of *Allen*, a preferred composition of the invention included about 0.57% leucine. At no place in the disclosure does *Allen* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims.

Further, *Phillips* is cited solely for the teaching that beta-hydroxy beta-methylbutyrate (HMB) is a metabolite of leucine and may help to build muscle. See, Office Action, page 36, lines 4-8. At no place in the disclosure does *Phillips* disclose or suggest compositions containing about 8% to about 10% of valine as required, in part, by the present claims.

For at least these reasons, Applicant respectfully submits that the obviousness rejection is improper and that the cited references fail to disclose or suggest each and every element of the present claim.

Accordingly, Applicant respectfully requests that the obviousness rejection of Claims 1-4, 7-11, 13-14, 16, 17 and 23-28 under 35 U.S.C. §103 be reconsidered and withdrawn.

In the Office Action, Claims 1 and 23-25 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,544,568 to Heyland et al. ("*Heyland*"). Applicant respectfully submits that *Heyland* is deficient with respect to the present claims.

Independent Claims 1 and 25 recite, in part, compositions having leucine, valine in an amount of about 8% to about 10% by weight based on the weight of total amino acids, a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids ranging from about 0.60 to about 0.90 and wherein the ratio of leucine in free and/or salt form to leucine in form of the intact protein is about 3:1 to about 1:3. Independent Claims 23-24 recite, in part, compositions consisting essentially of leucine in free and/or salt form, is present

in an amount of at least 30% by weight based on the weight of total amino acids, and valine in an amount of about 8% to about 10% by weight based on the weight of total amino acids. As discussed above, Applicant has surprisingly found that a formulation containing free essential amino acids as compared to a formulation containing free essential and non-essential amino acids or intact protein alone is optimal. See specification, Examples 1-2. Applicant has also found that nutritional compositions comprising a mixture of essential amino acids in free form and/or in salt form that has particularly high amounts of leucine had a stimulatory effect on muscle protein synthesis. See specification, Example 3. In contrast, Applicant respectfully submits that *Heyland* fails to disclose or suggest each and every element of the present claims.

Heyland fails to disclose or suggest compositions having leucine, valine in an amount of about 8% to about 10% by weight based on the weight of total amino acids, a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids ranging from about 0.60 to about 0.90 and wherein the ratio of leucine in free and/or salt form to leucine in form of the intact protein is about 3:1 to about 1:3 as required, in part, by independent Claims 1 and 25. *Heyland* also fails to disclose or suggest compositions consisting essentially of leucine in free and/or salt form, present in an amount of at least 30% by weight based on the weight of total amino acids, and valine in an amount of about 8% to about 10% by weight based on the weight of total amino acids, as required, in part, by independent Claims 23 and 24. Instead, *Heyland* discloses all essential amino and fails to recite any non-essential amino acids at any place in the disclosure. As such, *Heyland* cannot disclose or suggest a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids ranging from about 0.60 to about 0.90 as required, in part, by independent Claims 1 and 25.

Further, and as noted by the Patent Office, *Heyland* expressly discloses a composition having 150 g of technical leucine, 70 g of monosodium glutamate, 40 g of sodium chloride, 180 g of whey powder and 160 g of a casein hydrolysate. See, *Heyland*, column 6, lines 55-60. In contrast, the present claims use the transitional phrase of "consisting essentially of," which limits the scope of a claim to the specific materials or steps and those that do not materially affect the basic or novel characteristics of the claimed invention. See, MPEP 2111.02; *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976). The Federal Circuit has also characterized a "consisting essentially of" claim as occupying a middle ground between closed claims of "consisting of"

format and fully open claims of "comprising" format. See, *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Therefore, with regard to the present claims, the "consisting essentially of" language limits the composition to containing leucine, valine and an essential amino acid (Claims 1 and 23-24) or leucine, valine, an essential amino acid and an intact protein (Claim 25), and those materials that do not materially affect the basic or novel characteristics of the claimed invention. Applicant respectfully submits that the additional composition elements disclosed in *Heyland* materially affects the basic or novel characteristics of the claimed compositions. Accordingly, the "consisting essentially of" language of the present claims is closed language that excludes the additional elements of the compositions described in *Heyland*. As such, *Heyland* fails to disclose each and every element of the present claims and fail to even recognize the advantages of the presently claimed subject matter.

Further, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, *e.g.*, *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. In the instant case, the Patent Office has failed to identify disclosure in *Heyland* for each and every element of the present claims. Applicant submits that the Patent Office must be able to specifically identify the disclosure of each and every limitation of the claimed invention before anticipation may be found.

For at least these reasons, Applicant respectfully submits that the anticipation rejection is improper and that *Heyland* fails to anticipate the presently claimed subject matter.

Accordingly, Applicant respectfully requests that the anticipation rejection of Claims 1 and 23-25 under 35 U.S.C. §102 be reconsidered and withdrawn.

CONCLUSION

For at least the reasons set forth above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to deposit account no. 50-4498 in the name of Nestle Nutrition.

Respectfully submitted,

BY _____
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